

PATENT COOPERATION TREATY


PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 28 NOV 2005

Applicant's or agent's file reference PAC/ARB/22191		FOR FURTHER ACTION		See Form PCT/PEA/416	PCT
International application No. PCT/GB2004/002982		International filing date (day/month/year) 09.07.2004		Priority date (day/month/year) 09.07.2003	
International Patent Classification (IPC) or national classification and IPC A61M15/00					
Applicant CIPLA LIMITED et al.					
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 9 sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>					
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>					
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International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

3-28 as originally filed
1, 2, 2a received on 10.06.2005 with letter of 09.06.2005

Claims, Numbers

1-21 received on 10.06.2005 with letter of 09.06.2005

Drawings, Sheets

1/12-12/12 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 21

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 21 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 21

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1,5-8,11,20
	No: Claims	2-4,9,10,12-19
Inventive step (IS)	Yes: Claims	1,5-8,11,20
	No: Claims	2-4,9,10,12-19
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

1 Concerning Item III

It is unclear in claim 21 what kind of technical features should be defined by referring to the drawings. Therefore, they cannot be examined in respect of Article 33(2)-(4) PCT.

2 Concerning Item V

- 2.1 US-A-2002/0032409 (D1) discloses an inhaler device according to the preamble of claim 1. The features of the characterizing portion provide a simple and reliable actuation mechanism for a compact multidose inhaler device. The documents cited in the Search Report disclose different actuation mechanisms, but none of the documents discloses the technical features of the characterizing portion of claim 1. Consequently, the subject-matter of claim 1 appears to meet the requirements of Article 33(2) and (3) PCT.
- 2.2 D1 discloses an inhaler device comprising first and second components (12, 20) movable relative to one another, means (40) for receiving a medicament cartridge, medicament extraction facilitating means (30) and operating means (21, 23-27, 33, 44) as defined in claim 2. In addition, also US-A-5 388 573 (D2) and US-A-6 116 238 (D3) are considered to disclose inhalers which fall under the wording of claim 2. Consequently, the subject-matter of claim 2 does not meet the requirement of Article 33(2) PCT.
- 2.3 Furthermore, the technical features of dependent claims 3, 4, 9, 10 and 12-19 appear to be known from at least one of said documents. Thus, the subject-matters of said claims do not meet the requirement of Article 33(2) PCT.
- 2.4 The remaining claims 5-8, 11 and 20 do not appear to be derivable from any of the cited documents in an obvious manner. Thus, they appear to meet the requirements of Article 33(2) and (3) PCT.
- 2.5 The industrial applicability (Article 33(4) PCT) of a device according to the claims 1-19 is self-evident.

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(SEPARATE SHEET)**

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3 Concerning Item VII

- 3.1 Even though claim 1 has been drafted as a formally independent claim, it is effectively a dependent claim, because it includes all the technical features of claim 2.
- 3.2 The closest prior art (D1) has not been identified as required by Rule 5(a)(ii) PCT. Furthermore, the independent claims are not in the two-part form as required by Rule 6.3(b) PCT.

MULTI-DOSE INHALER

The present invention relates to inhalers for the administering of medicament. The invention relates particularly to multi-dose inhalers and more particularly to inhalers which are used with piercable sealed cartridges having a plurality of medicament compartments. Such inhalers allow for the administration of predetermined doses of medicament (typically a dry powder medicament).

A wide variety of multi-dose inhalers are presently available on the market and they are designed for the inhalation of predetermined multiple doses of medicament by a patient. One example of a conventional inhaler has top and bottom portions enclosing a circular cartridge of medicament comprising a plurality of cavities in which predetermined quantities of medicament are held. A spike member, operable by a user (e.g. a patient), is pressed down by hand and pierces a foil sealingly the cartridge. A patient may then inhale medicament through a mouthpiece. Once inhalation of medicament from one cavity is completed, a fresh medicament cavity is brought to an inhalation position by manually lifting the spike and then rotating the top portion relative to the bottom portion. It will be understood that, in using this type of inhaler, a user must perform multiple operations. These multiple operations render conventional types of inhaler extremely inconvenient to use.

An inhaler according to the preamble of the appended independent claim 1 is disclosed in US 2002/0032409.

An inhaler device is described below as comprising first and second components movable relative to one another; means for receiving a medicament cartridge comprising a plurality of compartments containing medicament; medicament extraction facilitating means for locating adjacent a

compartment of a received cartridge and thereby allowing an extraction of medicament therefrom; and operating means which, when activated by a user, advances a cartridge compartment of a received cartridge into a predetermined position relative to the medicament extraction facilitating means and extends the medicament extraction facilitating means into a position adjacent said advanced compartment for allowing medicament extraction upon inhalation by a user; wherein the operating means is mounted relative to said first and second components so as to be activated in response to said first and second components being moved relative to one another by a user.

It will be understood therefore that, in use of the inhaler device, a user moves first and second components relative to one another and, in so doing, advances a cartridge compartment containing medicament into an appropriate position relative to medicament extraction facilitating means, such as a spike, and also extends the medicament extraction facilitating means into a position allowing medicament to be extracted from the advanced compartment. Accordingly, as a result of a single action by the user, multiple operations are undertaken within the inhaler device. As such, the inhaler device is very convenient to use.

A first aspect of the present invention provides an inhaler device as recited in the appended independent claim 1.

A second aspect of the present invention provides an inhaler device as recited in the appended independent claim 2.

The appended dependent claims 3 to 20 define an inhaler device comprising further features of the present invention.

2a

Embodiments of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is an exploded cross-sectional side view of an inhaler device according to the present invention;

Claims:

1. An inhaler device (2) comprising first and second components (4, 6) movable relative to one another; means for receiving a medicament cartridge (12) comprising a plurality of compartments (140) containing medicament; medicament extraction facilitating means (14) for locating adjacent a compartment (140) of a received cartridge (12) and thereby allowing an extraction of medicament therefrom; and operating means (16, 28, 34, 40, 42, 44, 46) which, when activated by a user, advances a cartridge compartment (140) of a received cartridge (12) into a predetermined position relative to the medicament extraction facilitating means (14) and extends the medicament extraction facilitating means (14) into a position adjacent said advanced compartment (140) for allowing medicament extraction upon inhalation by a user; wherein the operating means is mounted relative to said first and second components (4, 6) so as to be activated in response to said first and second components (4, 6) being moved relative to one another by a user, and wherein the operating means comprises biasing means (16) for applying a force to a received cartridge (12) which, on activation of the operating means, advances said compartment (140) towards said predetermined position; the inhaler device (2) being characterised in that the cartridge receiving means and the cartridge biasing means (16) are secured to said first component (4), and in that the operating means further comprises two pins (34) which are each further secured to said first component (4) so as each to be movable between an extended position, in which the respective pin is engageable with a received cartridge (12) so as to limit the cartridge advancement caused by said biasing force, and a retracted position, in which the respective pin is spaced from a received cartridge (12) so as to not limit cartridge advancement.

2. An inhaler device (2) comprising first and second components (4, 6) movable relative to one another; means for receiving a medicament cartridge (12) comprising a plurality of compartments (140) containing medicament; medicament extraction facilitating means (14) for locating adjacent a compartment (140) of a received cartridge (12) and thereby allowing an extraction of medicament therefrom; and operating means (16, 28, 34, 40, 42, 44, 46) which, when activated by a user, advances a cartridge compartment (140) of a received cartridge (12) into a predetermined position relative to the medicament extraction facilitating means (14) and extends the medicament extraction facilitating means (14) into a position adjacent said advanced compartment (140) for allowing medicament extraction upon inhalation by a user; wherein the operating means is mounted relative to said first and second components (4, 6) so as to be activated in response to said first and second components (4, 6) being moved relative to one another by a user.

3. An inhaler device (2) as claimed in claim 2, wherein the operating means comprises biasing means (16) for applying a force to a received cartridge (12) which, on activation of the operating means, advances said compartment (140) towards said predetermined position.

4. An inhaler device (2) as claimed in claim 3, wherein the cartridge receiving means and the cartridge biasing means (16) are secured to said first component (4), and wherein the operating means further comprises two pins (34) which are each further secured to said first component (4) so as each to be movable between an extended position, in which the respective pin is engageable with a received cartridge (12) so as to limit the cartridge advancement caused by said biasing force, and a retracted position, in which

the respective pin is spaced from a received cartridge (12) so as to not limit cartridge advancement.

5. An inhaler device (2) as claimed in claim 1 or 4, wherein the operating means further comprises two camming members (44, 46) secured to said second component (6) which are each arranged so as to move a different one of the two pins (34) in response to said first and second components (4, 6) being moved relative to one another by a user.

6. An inhaler device (2) as claimed in claim 5, wherein said two pin camming members (44, 46) are arranged so as to ensure at least one pin is located in the extended position regardless of the position of said first component relative to said second component.

7. An inhaler device (2) as claimed in claim 6, wherein a space is provided between a medicament cartridge (12) and a pin (34) moved from a retracted position into engagement therewith, the space being such that, when a first pin (34) moves from an extended position into a retracted position, the space between the cartridge (12) and a second pin (34) engaged therewith is closed as the cartridge (12) advances under the bias of the biasing means (16).

8. An inhaler device (2) as claimed in any of the preceding claims, wherein the operating means retracts the medicament extraction facilitating means from adjacent said advanced compartment (140) when further activated by a user, wherein the operating means is mounted relative to said first and second components (4, 6) so as to be further activated in response to said first and second components being moved relative to one another by a user.

9. An inhaler device (2) as claimed in any of the preceding claims, wherein the medicament extraction facilitating means (14) is secured to said first component (4) so as to be movable between an extended position, in which the extraction facilitating means (14) is located adjacent a cartridge compartment (140) for allowing medicament extraction therefrom, and a retracted position, in which the extraction facilitating means (14) is spaced from said cartridge compartment (140) so as to not limit cartridge advancement; and the operating means comprises camming means (40, 42) secured to said second component (6) which is arranged so as to move the extraction facilitating means (14) in response to said first and second components (4, 6) being moved relative to one another by a user.

10. An inhaler device (2) as claimed in claim 9, wherein said camming means (40, 42) comprises two separate camming members (40, 42), a first (40) of which moves the extraction facilitating means (14) towards the extended position and a second (42) of which moves the extraction facilitating means (14) towards the retracted position.

11. An inhaler device (2) as claimed in claim 10, wherein the operating means comprises a lever (28) pivotally secured to said first component (4) and connecting the extraction facilitating means (14) to one of said two separate camming members (40, 42).

12. An inhaler device (2) as claimed in any of the preceding claims, further comprising counting means (148, 150) for indicating to a user the number of compartments (140) remaining to be advanced.

13. An inhaler device (2) as claimed in claim 12, wherein the counting means comprises a member provided with indicia and means for moving said member across a window when a compartment (140) is advanced.

14. An inhaler device (2) as claimed in any of the preceding claims, further comprising a mouthpiece (8) secured to one of said components (4, 6) and in fluid communication with the medicament extraction facilitating means (14), and a mouthpiece cover (10) secured to the other of said components (4, 6).

15. An inhaler device (2) as claimed in any of claims 1 to 13, comprising a mouthpiece (8) and a mouthpiece cover for covering the mouthpiece.

16. An inhaler device (2) as claimed in claim 15, wherein the mouthpiece cover is fixed to the mouthpiece so as to allow relative rotational movement of the mouthpiece and mouthpiece cover between a first configuration, in which the mouthpiece is covered, and a second configuration, in which the mouthpiece is uncovered.

17. An inhaler device (2) as claimed in any of the preceding claims, wherein the extraction facilitating means (14) comprises a fluid passage defining a venturi.

18. An inhaler device (2) as claimed in any of the preceding claims, wherein the extraction facilitating means (14) comprises means for piercing a compartment (140).

19. An inhaler device (2) as claimed in any of the preceding claims, wherein means are provided for preventing advancement of the cartridge (12) once the

medicament extraction facilitating means (14) has been located adjacent each compartment (140) of the cartridge (12).

20. An inhaler device (2) as claimed in any of the preceding claims, wherein a stop member is provided on the cartridge which, when engaged with a stop member provided on one of said first and second components, prevents movement of the cartridge (12) further than the last dose.

21. An inhaler device (2) as hereinafter described with reference to and as shown in the accompanying drawings.

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